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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,534	11/20/2001	Charles V. Lowry	0410008	9912

23405 7590 07/29/2003

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EXAMINER
LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,534	LOWRY, CHARLES V.	
	Examin r	Art Unit	
	David A. Lambertson	1636	

-- Th MAILING DATE of this communication appears on the cov r sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☒ Claim(s) *17-20 and 23-28* is/are allowed.

6)☒ Claim(s) *1-16,21,22,29 and 33-39* is/are rejected.

7)☒ Claim(s) *40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions.

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. Upon further consideration, and in view of applicant's arguments, Groups II-V have been rejoined with Group I. However, the examiner maintains the restriction requirement as it regards the rejoinder of Group VI with Groups I-V. The traversal is on the ground(s) that (a) the method of Group VI can only be performed with the plasmids as claimed in Groups I-V and (b) a search of Groups I-V will necessarily result in art as it regards the method claimed in Group VI. This is not found persuasive because of the following reasons:

A. Groups I-V and Group VI were previously restricted as having a product-process of using relationship; the standard for properly restricting a product and process of using the product relies on one of two issues: (1) the product must be able to be used in a materially different process *or* (2) the process must be able to use a materially different product. It is only necessary that one of these standards be met to establish a burden of search. Thus, applicant's argument that the method can only be practiced using the plasmids as claimed is moot if the plasmids can be used in a materially different process. This is true in the instant case, as the plasmids can be used in a materially different process, such as the cloning of different genes; this is supported in the following rejections of the claims, wherein plasmids that meet the limitations of the claims regarding the products are used for different processes. Furthermore, it was clearly set forth in the restriction requirement that the plasmids could be used for alternative processes. Therefore, the claims drawn to the plasmids/method of making and the claims drawn to a method of using the plasmids to monitor the efficiency of a restriction digest are properly restricted as a product

and a process of using. Therefore, this argument is not convincing to establish rejoinder of Group VI with Groups I-V.

B. A search of the plasmids does not necessarily result in the identification of art regarding a method of using the plasmids to monitor the efficiency of a restriction digest because the plasmids can be used in a materially different method. This is set forth above in (A), and is again supported by the following rejections wherein art is uncovered regarding the plasmids as claimed, but wherein the method of using those plasmids is different than the methods as claimed in Group VI. Therefore, this argument is not convincing to establish rejoinder of Group VI with Groups I-V.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed November 20, 2001 as Paper No. 3 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

Claim Objections

Claims 40 and 41 are objected to because of the following informalities: the claims recite figure numbers in the specification. It would be remedial to refer to the specific plasmids set forth in the figure legends by their plasmid name (e.g., pDM1, pDM2, etc.). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Before setting forth the rationale as to why Sikorski anticipates the instant claims, the examiner would like to set forth several issues regarding the interpretation of the claims. First, regarding the claims broadly, the term "polylinker" as described in the claims represents a short segment of nucleic acid having a plurality of restriction endonuclease recognition sites. In this context, a "plurality" is understood as being "more than one" (as per the definition of plural) and a "short segment of nucleic acid" is understood as being around 200 nucleotides in length, there being no clear definition of a "short segment of nucleic acid." Second, the recitation of the limitation "for use in monitoring the efficiency of a restriction endonuclease digestion: is an intended use and does not confer patentable weight to a plasmid that can be used for other purposes, in light of the fact that the claims are directed to the plasmid and not to a method of using the plasmid. Third, Claim 11 recites the limitation "wherein said plasmid is linearized prior to use in an endonuclease digestion reaction"; this limitation is not given any patentable weight because it is an intended use, and does not substantially describe or further limit the plasmid itself, therefore the claim is interpreted as if it were describing the plasmid as set forth in the dependent claim 1. Next, claims 21 and 22 are product-by-process claims, wherein the process confers no distinct chemical or structural distinction on the plasmids relative to the set of plasmids described in claim 12. Regarding claim 29, the method of producing plasmids for

monitoring the efficiency of a restriction endonuclease digest recites an intended use which carries no patentable weight with regard to the method of producing the plasmid; therefore the claim is interpreted simply as a method of producing the plasmids as claimed in a host cell. Finally, claims 33-39 are drawn to kit claims containing instructions; this is an intended use of the plasmids, and therefore holds no patentable distinction over the plasmids themselves as the invention is drawn to the composition, and not a method of using the composition.

Claims 1-16, 21, 22, 29 and 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski et al. (*Genetics* **122**: 19-27, 1989; see entire document; henceforth Sikorski).

Sikorski describes a set of four plasmids which meet the limitations set forth in claims 1-16, 21, 22,29 and 33-39 (see for example, Figure 2, page 22). Specifically, each of the plasmids comprises at least two short segments of nucleic acids comprising more than one restriction endonuclease site (e.g., a polylinker as set forth in the claims), wherein the digestion of the plasmids with two specific restriction endonucleases results in the production of two nucleic acid fragments that are substantially different in size from the intact plasmid due to the presence of a spacer segment between the two polylinker regions that is at least 50% the size of the full plasmid (see figure 4). In the interest of brevity, this principle will be demonstrated with respect to one of the plasmids set forth in figure 4, pRS303 (top left), although the same rationale can be applied to any of the other plasmids as well. Plasmid pRS303 comprises a first short segment of nucleic acid containing a number of restriction endonuclease recognition sites, beginning from nucleic acid 2073 and ending with nucleic acid 2175, and a second short segment of nucleic acid

containing at least two restriction endonuclease recognition sites, beginning with nucleic acid 1122 and ending with nucleic acid 1183. Plasmid pRS303 is a total of 4453 nucleic acids long. The distance between residue 2175 and 1122, then, is a total of 3418 nucleotides in length (4453-2157= 2296+1122= 3418); this indicates that the spacer segment between the two polylinker regions is ~77% (3418/4453= .767) of the length of the plasmid, which is easily greater than 50%. The same mathematical manipulations can be done with any of the either three plasmids with comparable results, using the following regions as the polylinker segments: pRS304- 1891-1993 (1^{st}) and 750-758 (2^{nd}); pRS305- 3124-3226 (1^{st}) and 1005-1116 (2^{nd}); pRS306- 2001-2103 (1^{st}) and 603-791 (2^{nd}). Additionally, each of these plasmids comprises at least one selectable marker (e.g., Ampicilin resistance) and a replication origin (e.g., *ori*), and the plasmids comprise the vector backbone of pBS (pBLUESCRIPT) (see for example page 19, right side, first full paragraph). Furthermore, Sikorski teaches that these plasmids can be produced in bacterial cells (see for example page 19, the section on "Bacterial strains and media"). Finally, although the inclusion of restriction enzymes and appropriate buffers as set forth in claims 38 and 39 is an intended use and carries no patentable weight with respect to the plasmids themselves, Sikorski describes the use of restriction enzymes to manipulate the plasmids set forth in figure 4. This necessarily includes the use of the appropriate buffer solutions when following the instructions set forth in the standard techniques referenced in the materials and methods section (see for example page 19, the section on "DNA manipulations" and page 21, the section on "Construction of new yeast integrating plasmids"). Therefore, Sikorski teaches all of the elements as set forth by the claims as indicated above.

Claims 1-16, 21, 22, 29, 33-36, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmeros et al. (*Gene* **247**: 255-264, 2000; see entire document; henceforth Palmeros).

It is noted that the claims are interpreted in the same manner as set forth above in the discussion of the Sikorski reference.

Palmeros describes a set of three plasmids, wherein the plasmids comprise two distinct polylinkers flanking two *loxp* sites which themselves flank either the *cat*, *ntpII* or *aacC1* genes (see for example the Abstract, page 257 section 2.3.1, and figure 1). The plasmids are generated from a pBR322 backbone, and comprise an origin of replication (e.g., ori_n) and a selectable marker (e.g., *cat*) (see for example figure 1). The size of the plasmids (named pCm^R (*cat*), pKm^R (*ntpII*) and pGm^R (*aacC1*) for convenient reference to the inserts), based upon the scale provided in figure 1 and the size of the inserts set forth on page 257 are as follows: pCm^R is 4423 nucleotides in length (3441 + 982 insert= 4423); pKm^R is 4619 nucleotides in length (3441 + 1178 insert= 4619); pGm^R is 4161 nucleotides in length (3441 + 720 insert= 4161). The spacer element, following digestion of each of the plasmids, would be ~3000 nucleotides in length. Therefore, each of the plasmids, when digested with any two restriction enzymes locates in the polylinker regions, would yield a fragment that was at least 50% of the size of the intact plasmid (pCm^R- 3000/4423= 67.8%, pKm^R- 3000/4619= 64.9%, pGm^R= 3000/4161= 72%). Palmeros also teaches using host cells to produce the plasmids in question, thereby anticipating a method of producing the plasmids (see for example page 256, section 2.1). Finally, although the inclusion of restriction enzymes and appropriate buffers as set forth in claims 38 and 39 is an intended use and carries no patentable weight with respect to the plasmids themselves, Palmeros

describes the use of restriction enzymes to manipulate the plasmids set forth in figure 1. This necessarily includes the use of the appropriate buffer solutions when following the instructions set forth in the standard techniques referenced in the materials and methods section (see for example page 257-258, section 2.4). Therefore, Palmeros teaches all of the elements as set forth by the claims as indicated above.

Allowable Subject Matter

Claims 17-20 and 23-28 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
July 27, 2003

PATENT EXAMINER
A.U. 1636